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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/270,437	03/16/1999	YAO-TSENG CHEN	LUD5538.1CIP	2508

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FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/20/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/270,437

Applicant(s)

Chen et al

Examiner

Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 108 and 110-147 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 110-125, 127, 128, 131-133, 135-140, 142, and 145-147 is/are allowed.
- 6) ☒ Claim(s) 108, 126, 129, 130, 143, and 144 is/are rejected.
- 7) ☒ Claim(s) 134 and 141 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☒ Other: **Notice To Comply**

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Response to Amendment

1. After review and reconsideration, the finality of the Office action of Paper No. 16 is withdrawn.
2. Claims 54-107 are canceled. Claims 143-147 have been added. Claims 108 and 110-147 are pending and under consideration.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
4. The rejection of claims 108, 129 and 130 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention due to the absence of sequence compliance is maintained, as the CRF submitted August 26, 2002 contains errors. Please see the attached CRF Problem Report.
5. Claims 143 and 144 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the same reasons of record as stated on page 8, section 10, of the Office action of Paper No. 12:

Claim 80 is vague and indefinite in the recitation of "an amino acid sequence of from 8 to 25 amino acids concatenated to each other in the isolated cancer associated antigen of claim 74". How this concatenation of undefined amino acids is supposed to occur within the context of the polypeptide encoded by SEQ ID NO:5-8 is unclear. For purpose of examination the claim will be read as --expression vector comprising a polynucleotide encoding 8 to 25 amino acids of the protein encoded by SEQ ID NO:5-8--."

Newly submitted claim 143 reads "an amino acid sequence of from 8 to 25 amino acids concatenated to each other in the protein encoded by the isolated nucleic acid molecule of claim 110". How this concatenation of undefined peptide fragments is supposed to occur within the context of the proteins encoded by the isolated nucleic acids of claim 110 remains unclear. It is

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unclear if “each other” is in reference to the amino acids, or to the peptides, and it is completely unclear how this concatenation is supposed to occur within the context of the protein encoded by the nucleic acids of claim 110. For purpose of examination, the claim will be read as an expression vector comprising a polynucleotide encoding 8 to 25 amino acids of the protein encoded by SEQ ID NO:5, 6, 7 or 8.

6. Claims 108, 129 and 130 and rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 108, 129 and 130 recite “nucleotide sequence defined by SEQ ID NO...”. The metes and bounds of what is “defined by” a sequence identifier is unclear. It cannot be ascertained if the nucleotide sequences “defined by” the sequence identifier comprise or consist of the SEQ ID NO, or if “defined by” allows for some degree of variation of the SEQ ID NO.

Claim 130 recites “kit useful in determining expression of a cancer associated antigen, comparing a separate portion of each of (i) the nucleotide sequences defined by SEQ ID NO:9 and 10, (ii) the nucleotide sequence defined by SEQ ID NO:11 and 12, and (iii) the nucleotide sequences defined by SEQ ID NO:13 and 14”. The recitation of “comparing” is unclear within the literal context of the sentence. Further, it is unclear if the “portion” refers to the physical containment of the nucleic acids of the kit, or if the “portion” refers to a fragment of the nucleic acid sequences.

7. Claim 129 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 108, and claim 141 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 139. Claim 129 is an exact duplication of claim 108 and claim 141 is an exact duplication of claim 139. Claim 134 is also a substantial duplicate of claim 132, as there is no difference in the scope of claims 134 and 132.. Claim 134 is drawn to an isolated nucleic acid of claim 110 which encodes the protein encoded by SEQ ID NO: 8. Claim 132 is drawn to an isolated nucleic acid of claim

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110 which encodes the protein encoded by SEQ ID NO:6. The specification teaches that SEQ ID NO:6 consists of 72 bp of 5' UTR, 1707 bp of ORF and 1543 bp of 3'UTR. The specification states that SEQ ID NO:8 is an "alternate form" of SEQ ID NO:6 (page 12, lines 15-18).

Comparison of SEQ ID NO:6 and 8 indicates that SEQ ID NO:8 is lacking 129 bp from the 3'UTR. Therefore, the proteins encoded from SEQ ID NO:6 and 8 would be identical. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

8. Claims 126, 143 and 144 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) Claim 126, added with the amendment filed Feb 26, 2002, introduces new matter in the specific embodiment of a fibroblast cell which was not contemplated by the specification or claims as originally filed.

(B) Claim 143 is drawn to a composition comprising an expression vector which encodes at least one peptide consisting of an amino acid sequence of from 8 to 25 amino acids concatenated to each other in the protein encoded by the isolated nucleic acid molecule of claim 110, and a pharmaceutically acceptable adjuvant. When given the broadest reasonable interpretation, the claim encompasses a vector encoding multiple fragments of the protein encoded by the nucleic acid of SEQ ID NO:5, 6, 7 or 8, wherein said fragments are of 8 to 25 amino acids and concatenated to each other. As such the claim reads on an expression vector wherein novel protein sequences are expressed via the concatenation of protein fragments which are not physically connected in the parent amino acid sequence. For instance, a nucleic acid encoding a 25 amino acid segment from the amino terminus of the protein encoded by SEQ ID NO:5 can be concatenated to a nucleic acid encoding a 25 amino acid segment from the carboxyl

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terminus of the protein encoded by SEQ ID NO:5 resulting in a nucleic acid sequence which was not represented in the nucleic acids encoding the protein encoded by SEQ ID NO:5. The claim does not provide a limitation regarding the function of the claimed expression vectors, nor does the specification teach a use for said expression vectors which would encode novel epitopes not present in the protein encoded by SEQ ID NO:5. The specification describes only SEQ ID NO:5, 6, 7 and 8, and one of skill in the art would be able to determine the nucleic acids encoding proteins encoded by SEQ ID NO:5, 6, 7 and 8, due to the degeneracy of the genetic code. However, the disclosure of SEQ ID NO:5, 6, 7 and 8 does not serve to anticipate expression vectors comprising nucleic acid sequences which result from various combinations of nucleic acids encoding 8 to 25 amino acids of the proteins encoded by SEQ ID NO:5, 6, 7, and 8. The specification does not provide teachings with regard to the specific nucleotide structure of the nucleic acids encompassed by the expression vectors, nor does the specification teach examples of the claimed expression vectors which would be representative of the genus. Since the specification fails to describe common attributes of the genus in terms of structure and function that identify members of the genus, and because the genus is highly variant encompassing isolated nucleic acid sequences combined in such a way as to result in a sequence which is not comprised in the isolated nucleic acid sequence of claim 110, the disclosure of SEQ ID NO:5, 6, 7 and 8 is not sufficient to describe the genus. One of skill in the art would reasonably conclude that the specification fails to provide a representative number of species to describe the genus. Thus, it can be concluded that the applicant was not in possession of the claimed genus.

9. All other rejections and objections as set forth in Paper No. 16 are withdrawn.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are

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unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

November 14, 2002


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1000